

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
DAYTON DIVISION

DAYTON AREA CHAMBER OF COMMERCE;
OHIO CHAMBER OF COMMERCE;
MICHIGAN CHAMBER OF COMMERCE; and
CHAMBER OF COMMERCE OF THE
UNITED STATES OF AMERICA,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES;
CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

Case No. 3:23-cv-00156-TMR-PBS

DECLARATION OF JAMES HOLCOMB IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

DECLARATION OF JAMES HOLCOMB

I, James Holcomb, declare as follows:

1. I am President & CEO of the Michigan Chamber of Commerce. In that capacity,

I am responsible for the strategic direction and oversight of the Michigan Chamber of Commerce from both a financial and operational perspective.

2. The purpose of this declaration is to discuss the effects of the price control provisions of the Inflation Reduction Act on the Michigan Chamber's members and the irreparable harm that will result if the provisions are not enjoined.

3. Unless otherwise stated, this Declaration is based upon my personal knowledge and belief and/or upon my review of business records of the Michigan Chamber. If called as a witness, I could and would testify competently thereto.

I. The Michigan Chamber's Mission and Members

4. The Michigan Chamber of Commerce is Michigan's leading state-wide business advocacy organization, representing approximately 4,000 members who employ more than 1 million people. Its membership includes businesses big and small, trade associations, and local chambers of commerce representing all 83 Michigan counties and a variety of industries. For over 60 years, the Michigan Chamber has been a champion for good public policy. Using its voice to advance member priorities through legislative, legal, and political action, the Michigan Chamber's goal is to achieve policies that benefit members, their employees, and in turn the people of the State of Michigan by enhancing the quality of life for Michigan families.

5. The Michigan Chamber has members who will be directly subject to the IRA's price controls and whom market analysts expect will have drugs listed among the ten drugs selected by the Secretary for the IRA's price controls by September 1, 2023. The Michigan Chamber's members whose drugs are selected will be forced to enter "negotiations" with the Secretary, disclose competitively sensitive proprietary information to the Secretary, and "agree" to the Secretary's unreasonably low so-called "maximum fair price," which the Secretary can set without any statutory guarantee of a fair return on investment and without any administrative or judicial review. Because the statute sets a ceiling on such prices of at least 25 to 60% below market-price benchmarks, the price will be substantially lower than current market prices.

6. The Michigan Chamber is concerned about the financial threat of rising health care costs to Michigan's businesses. To improve the health care system for all Michigan

businesses and their employees, the Michigan Chamber advocates for market-friendly, consumer-driven reforms that will enable job providers and individuals to purchase affordable coverage in the private health insurance market. The Michigan Chamber opposes state and federal regulations that discourage innovation and deny its members a fair return on their investments in the health care space.

II. The Impact of the Price Control Provisions of the IRA

7. As President & CEO at the Michigan Chamber, I have worked to understand how the price-control system would affect member businesses and the substantial and irreparable harm that will result from it.

8. The federal government is both regulator and dominant market participant in the healthcare field. Medicare, Medicaid, and other federal health programs account for nearly half of the nation’s total healthcare expenditures, while the Department of Health and Human Services and the Centers for Medicare and Medicaid Services wield extensive authority over the federal health care programs. The Michigan Chamber’s members participate in these markets and, as a practical matter, must do so. Even if the members were willing to cut themselves off from approximately half of the nation’s market, the relevant statutory and regulatory provisions do not allow members currently participating in Medicare or Medicaid to exit these programs immediately.

9. The Inflation Reduction Act (IRA), passed in August 2022, requires HHS to establish what the statute calls a “Drug Price Negotiation Program,” 42 U.S.C. § 1320f(a). Under that program, the Secretary must publish, by September 1, 2023, the ten Medicare Part D drugs selected for “negotiation.” 42 U.S.C. § 1320f(d)(1). By October 1, 2023, manufacturers of selected drugs must sign “agreements” to “negotiate.” *Id.* § 1320f(d)(2)(A). By October 2,

2023, manufacturers must submit extensive data requested by the Secretary. *Id.*

§ 1320f(d)(5)(A). By February 1, 2024, HHS will send to each manufacturer the government’s initial “offer” of what it would establish as the “maximum fair price” for a specific drug. *Id.*

§ 1320f(d)(5)(B). By March 2, 2024, each manufacturer must either accept HHS’s offer or send a “counteroffer.” *Id.* § 1320f-3(b)(2)(C)(i). By August 1, 2024, HHS must decide the price that it is imposing. It then publishes the price as the “maximum fair price” by September 1, 2024, and the price goes into effect on January 1, 2026. *Id.* § 1320f(d)(5)-(6). The process will repeat annually, with additional drugs being selected each year. *Id.* § 1320f(b)(3). The prices imposed by HHS continue in effect until HHS determines that a generic or biosimilar version of the drug is approved or licensed and marketed pursuant to that approval or licensure. *Id.* § 1320f-1(c)(1).

10. The IRA contains no standard by which HHS should set the price, except that it should “achieve the lowest maximum fair price for each selected drug.” *Id.* § 1320f-3(b)(1). The statute does not set any threshold for what the “maximum fair price” must be; it simply defines the “maximum fair price” as whatever price the Secretary sets. Although permitting a manufacturer to “counteroffer” based on certain specified factors, the statute provides no standard for HHS to apply in considering such a counteroffer. HHS is free to reject the counteroffer and set whatever price it likes in its unreviewable discretion.

11. The IRA bars administrative and judicial review of the key determinations in this price-control scheme, including the selection of drugs and the determination of a maximum fair price. *Id.* § 1320f-7.

12. Multiple Michigan Chamber members will be subject to this price-control scheme, including by manufacturing drugs that market analysts expect to be on the first list, announced by September 1, 2023. They are facing critical decisions now about whether to

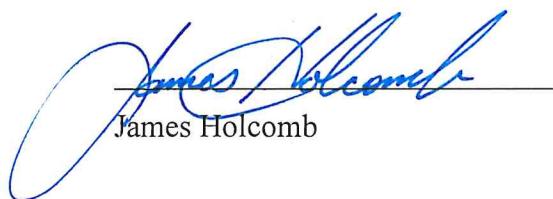
launch new research and/or continue existing research into potentially life-changing medicines, recognizing that it costs billions of dollars to discover new drugs, conduct rigorous pre-clinical and clinical testing, and shepherd drugs through the lengthy FDA approval process. This new price-control scheme provides no guarantee that the manufacturers will even be able to recoup the costs of their investments, much less to ensure a fair return on those investments.

III. Enjoining the Price-Control Provisions of the IRA Would Remedy Harms to Members

13. Enjoining the price-control provisions of the IRA would remedy the above-referenced harms to the Michigan Chamber’s members. It would enable them to avoid being exposed to confiscatory pricing and to continue to sell their products at market-based prices. It would also enable them to make investment decisions now to support innovation—investment decisions that would otherwise be put on hold, or decided adversely, because of uncertainty about their ability to recoup investment. And it would avoid the loss of customer goodwill that would accompany any effort to recoup losses later or that would accompany the government’s declaration that a substantially below market price is the “maximum fair price” for the member’s products.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 10th day of July at Lansing, Michigan.



James Holcomb